



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HFJ 35

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

AUG 31 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 79-00

Mr. Son Q. To, Co-Owner
Mr. Ha T. Tang, Co-Owner
Orange Bean Sprout
124 North Sullivan Street, # E-H
Santa Ana, CA 92703

Dear Mr. To and Mr. Tang:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 124 North Sullivan Street, Santa Ana, CA on July 5 and 6, 2000. The inspection revealed that your sprouts are adulterated within the meaning of 402 (a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. The sprouts are considered adulterated since effective controls, particularly microbial testing for pathogens, have not been adopted and implemented by your firm.

In the case of ready-to-eat sprouts, the agency has determined that microbial testing for *Salmonella* and *Escherichia coli* 0157:H7 is necessary and should be conducted (and found negative) prior to release of these food products into domestic commerce, and that this testing is an appropriate quality control operation. Our current guidance recommends that this testing should be conducted on the spent irrigation water used in the production of each lot of sprouts at specific growing periods, and is the most effective means to detect these harmful bacteria in the food. A production lot or batch is defined as sprouts from a single lot of seed that was started at the same time in a single growing unit (e.g. a single drum, or rack of trays).

Furthermore, our inspection revealed an additional insanitary condition that could constitute the products processed under such condition to be adulterated. This condition and practice included:

- Failure to handle Mung bean sprouts in a manner that protects against contamination. Specifically, baskets containing Mung beans prior to bagging were stacked on top of each other, with the bottom of the basket laying on top and directly contacting uncovered Mung bean sprouts. Additionally, these baskets were observed being stored directly on the wet and dirty floor in the processing and packaging rooms.

A copy of the guidance document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," is enclosed. This guidance document is intended to assist sprout manufacturers in implementing one of the principal recommendations in the guidance document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds," which is also enclosed.

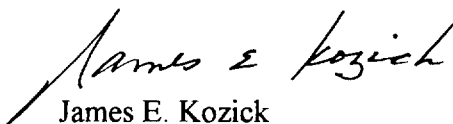
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

For your information, we also observed that your firm does not apply any antimicrobial treatment to your Mung bean seeds prior to sprouting. Please note that FDA currently recommends but does not require the treatment of pre-washed seed with 2% (20,000 ppm available chlorine) calcium hypochlorite solution for 15 minutes at room temperature with continuous agitation. The ratio of five (5) pounds seed in one gallon 2% calcium hypochlorite solution is recommended. This treatment has been approved for such use by the Environmental Protection Agency (EPA) [Ref: EPA Reg. #1258-427]

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be directed to the Director, Compliance Branch, U.S. Food & Drug Administration, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612-2445.

Sincerely,



James E. Kozick
Acting District Director

Enclosures:

Guidance to Industry Document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"

Guidance to Industry Document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds"

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief